PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

SYNDOL Tablets

Codeine Phosphate 10 mg

Doxylamine Succinate 5 mg

Paracetamol 450 mg

Caffeine 30 mg

Sugar Free

Read all of this leaflet carefully because it contains important information for you

SYNDOL Tablets is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SYNDOL Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SYNDOL Tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What SYNDOL Tablets is and what it is used for

2. What you need to know before you take SYNDOL Tablets

3. How to take SYNDOL Tablets

4. Possible side effects

5. How to store SYNDOL Tablets

6. Contents of the pack and other information

1. What SYNDOL Tablets is and what it is used for

SYNDOL TABLETS are indicated for the symptomatic relief of tension headache and other somatic

pain/tension states such as neuralgia, primary dysmenorrhoea and following trauma and surgery. SYNDOL TABLETS calm and soothe the patient and help allay the anxiety that can prolong or aggravate pain.

2. What you need to know before you take SYNDOL Tablets

Do not take SYNDOL Tablets

- if you are hypersensitive (allergic) to codeine phosphate, doxylamine succinate, paracetamol, caffeine or any of the other ingredients of SYNDOL Tablets (listed in section 6).
- If you taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- if you are taking other medicines containing codeine or any other paracetamol-containing medicines.
- If you suffer from shortness of breath, accompanied by a bluish discoloration of the skin especially and excessive mucous from the chest.
- After operations on the bile duct,
- if you suffer from alcoholism
- if you have had head injuries and conditions in which pressure in the head is raised. Signs of this include headaches, being sick (vomiting) and blurred eyesight.
- During an asthma attack or in heart failure secondary to chronic lung disease.
- if your kidney or liver function is severely impaired.
- if you have been told by your doctor that you have a metabolic disorder called acute intermittent porphyria. Signs include severe abdominal pain, constipation or diarrhoea, nausea and vomiting, and pain in your chest, legs or back.
- if you are at risk of blocked intestine (paralytic ileus)
- if you have been told by your doctor that you are a patient who is known to break down (metabolize) medications very quickly due to a specific enzyme (CYP2D6 ultra-rapid metabolisers)
- If your child is under 12 years old.
- If you are breastfeeding
- If you are in third trimester of pregnancy.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

SYNDOL Tablets contains codeine, which is an opioid medicine.

Repeated use of SYNDOL Tablets may result in you becoming accustomed to it (needing to take higher doses). Repeated use of SYNDOL Tablets may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you experience any of the following signs whilst taking SYNDOL Tablets, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')

Special care should be taken with SYNDOL Tablets:

- as this product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.
- Do not use continuously for more than 10 days without consulting your doctor.
- Consult your doctor if no relief is obtained with the recommended dosage.
- Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.
- This medicine may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.
- if you have high blood pressure or any heart problems.
- if you have trouble to pass urine.
- In patients suffering from liver or kidney disease should take paracetamol under medical supervision.
- if you suffer from myasthenia gravis, a condition which weakens the muscles.

- if you suffer from active stomach ulcers.
- In patients with low thyroid function, Addison's disease (low levels of cortisol and aldosterone), liver damage, enlarged prostate or shock.
- In patients with inflammatory or obstructive bowel disorders
- if you have had a recent operation on the gastrointestinal tract.
- if you have gall stones.
- if you suffer from seizures.
- Dosage should be reduced in elderly and debilitated patients.
- Tolerance dependence, and addiction: Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders
- if you are taking a benzodiazepine (used for treatment of anxiety or sleep disorders), e.g. diazepam, clobazam, lorazepam, chlordiazepoxide, oxazepam, temazepam, nitrazepam, loprazolam, lormetazepam or clonazepam
- if you have low glutathione reserves
- if you have Glucose-6-phosphate-dehydrogenase deficiency
- if you have Gilbert's syndrome
- if you have chronic constipation
- if you suffer from life threatening skin reactions such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).
- if you develop a red, scaly widespread rash with bumps under the skin and/or blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the start of treatment (acute generalized exanthematous pustulosis).
- if you develop a skin rash, swelling of lymph nodes and increase of eosinophils (a type of white blood cells). This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- if you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching.
- if you have a history of mental health disorders (difficulty in thinking, understanding and judging clearly which causes loss of touch with reality), if you have depression, anxiety and suffer from alcohol and drug abuse.
- Opioid Induced Hyperalgesia: Taking a high dose of opioid medications can paradoxically induce

or sensitise patients to acute pain, this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).

- in patients with glaucoma (increased pressure in the eye ball)
- Due to its codeine content, you should not take SYNDOL Tablets if you have any respiratory problems.
- Use in children with breathing problems: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced.

If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Children and adolescents

Do not give SYNDOL Tablets to children 12 years old and younger.

Other medicines and SYNDOL Tablets

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Do not take this medicine and tell your doctor or pharmacist, if you are taking:

- Monoamine oxidase inhibitors or within 14 days of stopping such treatment. MAOIs are medicines such as moclobemide, phenelzine, tranylcypromine.

Tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines:

- Metoclopramide, domperidone used to treat nausea and vomiting.

- Medicines used to thin the blood such as warfarin (or other coumarins).
- Medicines which make you drowsy or sleepy (CNS depressants) (e.g. barbiturates, anaesthetics, hypnotics, other opioid analgesics, anxiolytic sedatives, antipsychotics, tricyclic antidepressants and phenothiazines) or a benzodiazepine used to treat anxiety or sleep disorders.
- Medicines for the treatment of high blood pressure (diuretics and antihypertensives).
- Medicines to treat or prevent clinical depression (antidepressants).
- Medicines used to treat mental distress or disorder (antipsychotics).
- Any of the group called antimuscarinics (e.g. atropine, hyoscine).
- Any of the group called neuromuscular blockers (e.g. tubocurarine).
- Cholestyramine used for lowering blood cholesterol levels.
- Hydroxyzine used to treat anxiety and tension.
- Mexiletine used to treat irregular heartbeat.
- Kaolin or loperamide used for the treatment of diarrhoea.
- Naloxone used to treat a narcotic overdose.
- Naltrexone used as part of a treatment program for drug or alcohol dependence.
- Cimetidine used to treat stomach ulcers.
- Cisapride used to treat gastro-oesophageal reflux disease.
- Quinidine used to treat irregular heart rate.
- Theophylline – used for wheezing or difficulty in breathing
- Medicines for infections (antibiotics) such as enoxacin, ciprofloxacin, rifampicin and flucloxacillin
- The oral contraceptive pill
- Cinacalcet – to treat thyroid problems
- Methadone – used for treating drug (opioid) dependence and severe chronic pain.

Concomitant use of opioids and benzodiazepines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, you should only take these together if prescribed by a doctor. Please follow your doctor's dosage recommendation closely.

SYNDOL Tablets with food and drink and alcohol

SYNDOL Tablets should not be taken together with alcohol. The combined effect can cause major

drowsiness and severely impaired breathing, concentration, vision, speech and alertness.

Avoid drinking too much coffee, or other drinks containing caffeine, while taking SYNDOL Tablets.

Pregnancy and breastfeeding and fertility

SYNDOL Tablets should not be used during pregnancy or when breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

Patients should be cautioned about operating vehicles or machinery or engaging in activities which requires them to be fully alert.

It is not always possible to predict to what extent SYNDOL Tablets may interfere with the daily activities of a patient. Patients should ensure that they not engage in the above activities until they are aware of the measure to which SYNDOL Tablets affects them.

3. How to take SYNDOL Tablets

Do not share medicines prescribed for you with any other person.

Always take SYNDOL TABLETS exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 12 years and older: 2 tablets every 4 hours as needed.

Do not exceed 8 tablets per day.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more SYNDOL TABLETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.

Signs of overdose may include unusually pale skin, nausea, vomiting, loss of appetite, abdominal pain, pupils that may be pin-point in size, a difficulty in breathing, an increased or irregular heart rate, and loin (kidney) pain.

• Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too

much paracetamol can cause delayed, serious liver damage.

• Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you forget to take SYNDOL Tablets

Do not take / receive a double dose to make up for forgotten individual doses.

4. Possible side effects

SYNDOL Tablets can have side effects.

Not all side effects reported for SYNDOL Tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SYNDOL Tablets, please consult your health care provider for advice.

If any of the following happens, stop taking/giving SYNDOL Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SYNDOL Tablets. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- low number of white blood cells. Signs include: fever, chills, sore throat;
- low number of cells involved with blood clotting. Signs include: more or worse bruises than normal, small purple or red dots under your skin, nosebleeds or bleeding gums, black or bloody-looking bowel movements, red or pink urine;
- an excessive breakdown of red blood cells causing a type of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes;
- low number of red blood cells, white blood cells and cells involved with blood clotting. Signs include:

weakness, tiredness, skin problems such as rashes or bruising, rapid heart rate, shortness of breath;

- changes in mood, anxiety, feeling depressed, confusion;
- perceptions of having seen, heard, touched, tasted or smelled something that wasn't actually there;
- seizures;
- slowing down of the central nervous system. Signs include: slower heart rate and breathing, extreme confusion and memory loss and poor judgement;
- increased pressure in the head. Signs include headache, blurred vision, feeling less alert than usual and vomiting;
- blurred vision, constriction of the pupil of the eye;
- ringing in the ears;
- changes in the way your heart beats, drop in blood pressure when standing up making (causing light-headedness or fainting);
- yellowing of the skin, whites of the eyes and mucous membranes (jaundice);
- difficulty in urinating, inability to empty all the urine from your bladder;
- sudden drop in body temperature;
- skin rash or itching, which may include redness, hives (red itchy bumps), blisters, pustules or peeling of the skin (Toxic Epidermal Necrolysis) and bleeding in the lips, eyes, mouth, nose and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson Syndrome);
- a red, scaly, widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (Acute Generalised Exanthematous Pustulosis);
- a severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells);
- Fixed Drug Eruptions (FDE) (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching.
- SYNDOL Tablets, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment.

Signs and symptoms include muscle weakness and light-headedness.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- insomnia, deep sleep, drowsiness
- incoordination,
- dry mouth,
- nervousness,
- tremors, convulsions
- facial flushing

Less frequent:

- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Frequency not known:

- Restlessness
- sores in the mouth
- Decreased libido
- Lack of energy
- Sensitivity to light
- Tingling or prickling, “pins-and-needles” sensation in the arms, hands, legs or feet
- involuntary shaking of the hands, legs, face, head or vocal cords
- thick phlegm
- heartburn, diarrhoea, stomach pain, painful muscles
- fever
- hair loss
- reddening of the face
- Allergy/anaphylaxis
- Sweating

- pain in lower back area, puss in the urine, difficulty passing urine
- constipation

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SYNDOL TABLETS. You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store SYNDOL Tablets

Store all medicine out of reach of children.

Store at or below 25 ºC.

Do not use after expiry date stated on the label.

6. Contents of the pack and other information

What SYNDOL Tablets contains

SYNDOL TABLETS contains the active ingredient Codeine phosphate10 mg, Doxylamine succinate 5 mg, Paracetamol 450 mg and Caffeine 30 mg.

The other ingredients are:

Croscarmellose sodium, maize starch, povidone

SYNDOL Colour Lubricant consists of Colour Yellow 14037, magnesium stearate, purified talc and pregelatinised starch.

What SYNDOL Tablets looks like and contents of the pack

Round, yellow, scored tablet embossed with “S” logo on opposite side.

Blister packs consisting of clear, transparent, non-toxic, well thermos formable, food grade PVC film and printed aluminium foil with VMCH coating bright side.

Blister packs of 10, 18, 20, 40 tablets.

Not all pack types and pack sizes may not be marketed

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Access to the corresponding professional information

It is contained in the packaging of the medicine

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